

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE LITIGATION

MDL No. 1456

THIS DOCUMENT RELATES TO:

CIVIL ACTION: 01-CV-12257-PBS

ALL ACTIONS

Judge Patti B. Saris

**PLAINTIFFS' STATUS REPORT FOR THE AUGUST 3 CONFERENCE
AND PROPOSAL REGARDING THE TRACK 1 TRIAL**

I. INTRODUCTION

At the July 6, 2006 hearing, which primarily focused on class notice issues, the Court and the parties discussed whether a trial of certain issues relating to the Track 1 Defendants could begin in November, 2006. The Court has scheduled a hearing for August 3, 2006, in order to discuss those issues in greater detail. Plaintiffs respectfully submit this brief in advance of that hearing in order to address certain issues raised by the Court.

If the Court decides to start trial on some issues in November relating to Class 2, the Court will need to try the full Class 2 liability case. The Court has questioned whether it makes sense to try *only* purported TPP “knowledge” issues in November. Plaintiffs submit that it cannot, because purported TPP “knowledge” has no relevance to the objective inquiry under Chapter 93A that focuses on Defendants’ unfair or deceptive conduct and not the conduct of Plaintiffs and the Class. To prove a violation of Ch. 93A, Plaintiffs will introduce, among other things, evidence of Defendants’ phony AWP’s, the “real” ASPs, and Defendants’ spread marketing activities. In the Medicare Part B context, as at issue in the proposed Class 2 trial,

TPP “knowledge” is especially irrelevant where Class members by statute simply pay a percentage of AWP as a co-pay, Class Order at 47, and where the Court has decided to statutorily define AWP.

Furthermore, Class 3 purported “knowledge” issues should not be tried in tandem with Class 2 issues. The Court has indicated that it will “statutorily define AWP” for Classes 1 and 2. Therefore, the Class 2 trial will be driven by the Medicare Part B statute and not general market expectations that will be at issue in the Class 3 trial. If the Court decides to have a Class 2 trial in November, it should try the Class 2 liability issues only, unburdened by Class 3 issues. In other words, engrafting the Class 3 trial onto the Medicare Part B Classes shifts the focus from the statutory reimbursement regime to one that is market-driven and can lead to confusion.

Alternatively, the Court should defer the beginning of trial to March. Trying the Class 2 claims in November and then the Class 1 claims in March will lead to a repeat trial, as the vast majority of liability and damages evidence will have to be repeated in the Class 1 trial. It is not sensible to try the Class 2 claims without also reaching the Class 1 issues, particularly since the Court is not contemplating the presence of a jury in November. Holding a coordinated, omnibus trial in March is also more efficient because the parties will then be able to produce their trial plan having the benefit of the Court’s complete summary judgment and *Daubert* rulings.

Plaintiffs also recommend that the Court, as it is now contemplating, try the case against all Track 1 Defendants jointly, instead of trying each case against each of the Track 1 Defendants *ad seriatim*, which would entail much duplication in the presentation of fact and expert evidence. This will avoid the repeated introduction of testimony and other evidence relating to, *inter alia*, topics such as the Medicare Part B program, the structure and participants in the Medi-Gap

insurance market, Defendants' conduct, and expert testimony on matters of general applicability, such as general liability and damages models for Classes 1 and 2.

Lastly, the Court should entertain other ideas to promote the most efficient trial of this case, including limiting the number of experts that the Track 1 Defendants can use for common issues and placing a total time limit on each side for all direct and cross-examination.

II. IF THE COURT BEGINS TRIAL IN NOVEMBER, IT SHOULD TRY THE FULL CLASS 2 CASE

Given the duration of this litigation, the Court has stated that it would like to begin the trial of at least some issues this Fall. While at first blush the prospect of finally starting the trial of targeted issues is enticing to both the Court and Plaintiffs, closer analysis reveals that doing so is not possible. Should trial begin in November, it will necessarily involve the full Class 2 liability case, that is, the nature and scope of Defendants' conduct and whether the same is unlawful under Chapter 93A. Looking to try some subset of purported TPP "knowledge" issues is not sensible since knowledge issues are not relevant to the Class 2 trial. Again, the objective inquiry to be made by the Court under Ch. 93A focuses solely on *Defendants' conduct*; so will the evidence.

A. Carving Out And Trying So-Called TPP "Knowledge" Issues In The First Instance Is Inappropriate And Unworkable

The Court has discussed the possibility of trying only Class 2 and 3 TPP "knowledge issues" in November in order to "create some sort of industry-wide standard for when a company knew or should have known based on what was available in the industry." *See, e.g.*, July 6 Hearing Tr. at 67. This is both inappropriate and unworkable for a number of reasons.

Varying levels of sophistication and knowledge amongst TPPs are not relevant to deciding whether Defendants have committed unfair or deceptive acts or practices in violation of

Chapter 93A. An act or practice is **unfair** if it (i) is within at least the penumbra of some common-law, statutory, or other established concept of unfairness; (ii) is immoral, unethical, oppressive or unscrupulous; and (iii) causes substantial injury to consumers, competitors or other business people. *PMP Assocs., Inc. v. Globe Newspaper Co.*, 366 Mass. 593, 596, 321 N.E.2d 915 (1975) (citing *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 244 (1972)). Whether a given practice runs afoul of these touchstones must be determined from the circumstances of each case. *Levings v. Forbes & Wallace, Inc.*, 8 Mass. App. Ct. 498, 504, 396 N.E.2d 149 (1979). These inquiries necessarily focus on the defendants' conduct, and not the conduct of the plaintiff, and should be determined on a classwide basis.

An act or practice is **deceptive** if it possesses a capacity or tendency to deceive the general public. *Aspinall v. Philip Morris Cos., Inc.*, 442 Mass. 381, 396, 394, 813 N.E.2d 476 (2004); *Leardi v. Brown*, 394 Mass. 151, 156, 474 N.E.2d 1094 (1985).¹ This standard includes ““that vast multitude which includes the ignorant, [the] unthinking, and the credulous, who, in making purchases, do not stop to analyze but too often are governed by appearances and general impressions.”” *Aspinall*, 442 Mass. at 395 (quoting *Beneficial Corp. v. FTC*, 542 F.2d 611, 618 n.11 (3d Cir. 1976)). Importantly, the standard for deception is an **objective** one that does not depend on an inquiry into the individual circumstances of each class member. In *Aspinall*, a

¹ See also 940 C.M.R. § 3.04 (“No claim or representation shall be made by any means which has the capacity or tendency or effect of deceiving buyers or prospective buyers as to the value or the past, present, common or usual price of a product, or as to any reduction in price of a product, or any saving relating to a product.”); 940 C.M.R. § 3.05(1) (“No claim or representation shall be made by any means concerning a product which directly, or by implication, or by failure to adequately disclose additional relevant information, has the capacity or tendency or effect of deceiving buyers or prospective buyers in any material respect.”). These Attorney General regulations have the force of law, and violations of them constitute violations of G.L. ch. 93A. *Purity Supreme, Inc. v. Attorney Gen.*, 380 Mass. 762, 775, 407 N.E.2d 297 (1980). “In determining whether an act or practice is deceptive, ‘regard must be had, not to fine spun distinctions and arguments that may be made in excuse, but to the effect which it might reasonably be expected to have upon the general public.’” *Leardi*, 394 Mass. at 156 (quoting *P. Lorillard Co. v. FTC*, 186 F.2d 52, 58 (4th Cir. 1950)). The plaintiff need not prove that the defendant intended to deceive the plaintiff. *Aspinall*, 442 Mass. at 394. Nor is proof of reliance required, or even knowledge on the part of the defendant that the representation was false. *Id.*

false advertising case under Ch. 93A challenging Philip Morris's representations that "light" cigarettes delivered "lowered tar and nicotine," defendants urged causation inquiries into each smoker's individual smoking habits. 442 Mass. at 393-94. The court rejected this assertion, explaining that "[w]hether conduct is deceptive is initially a question of fact, *to be answered on an objective basis and not by the subjective measure argued by the defendants.*" *Id.* at 394 (emphasis added). Thus, the capacity or tendency to deceive test focuses on the effect that the challenged practice may reasonably be expected to have *on the general public.* *Id.*²

These principles apply here. Whether Defendants committed unfair or deceptive acts or practices in violation of Ch. 93A will turn on evidence that is common to all class members and not on an inquiry into the idiosyncratic and subjective knowledge of various Massachusetts TPPs. The focus of this inquiry will be on Defendants' reporting of inflated WACs and AWP, the calculation of Defendants' real ASPs, and Defendants' promotion of the spreads created at the expense of the Class. The entire Medicare Part B reimbursement landscape was infected by Defendants' misrepresented AWP; this is the impact on the general public that Chapter 93A seeks to remedy.

Whether a particular TPP was sufficiently sophisticated to realize the full extent of the secret spreads at issue here is therefore not the proper inquiry in making the unfair or deceptive determination under Ch. 93A, notwithstanding the fact that there is no evidence that a single TPP ever had such a realization. Moreover, because the Court has indicated that it will adopt a

² Turning next to the issues of class injury, the Court explained that an appropriate model under Ch. 93A encompasses demonstrating that, as a result of defendants' deception, all consumers paid more than they otherwise would have. *Id.* at 398-99. And the Court carefully differentiated between proving actual injury and individual damages, commenting that the two concepts should not be confused. *Id.* at 402. Injury can be demonstrated via common impact, even if individual damages are more complex: "Difficult issues with respect to determining the appropriate amount of actual or statutory damages to be awarded in a class action, or potential difficulties with the distribution of the aggregate damages award, do not preclude class certification when all other requirements are met." *Id.*

statutory definition of AWP for Class 2 (and Class 1), TPP awareness of what AWP meant outside of the Medicare Part B context has absolutely no bearing on what AWP meant within Medicare Part B. Furthermore, what a TPP did or did not know about spreads on Subject Drugs also has no bearing on the meaning of the AWP benchmark used by Medicare. There is no reason for any individual inquires on this issue for Class 2.

In sum, the proper inquiry under Ch. 93A focuses on Defendants' conduct, making it necessary to begin any trial of the Class 2 claims with a full presentation of Plaintiffs' liability case. There are no issues to carve-out in the manner initially suggested by the Court.

B. The Class 3 Claims Should Be Tried After The Claims Of Classes 1 and 2

The Court has also discussed trying at least some aspect of the Class 2 and 3 claims together – to wit, the purported “knowledge issue” – but this could lead to jury confusion. The expectations theory relevant to Class 3 is not relevant to Classes 1 and 2 given that the Court has indicated that it will “statutorily define AWP” for Classes 1 and 2. *See* July 6 Hearing Tr. at 52. Consequently, trying some of the Class 3 claims simultaneously with Class 2 shifts the focus from the statutory reimbursement regime to one that is market-driven.³ It is therefore more sensible and appropriate to try the Class 1 and 2 claims together without injecting Class 3 issues.

³ It bears noting that the Court may be under the misimpression that any knowledge on the part of TPPs can be imputed to the consumer members of Class 3 (*see* July 6 Hearing Tr. at 63), such that findings with regard to statute of limitations issues *vis-à-vis* TPPs, for example, will apply to plan members. But no such imputation can be accomplished absent the difficult showing that an agency relationship existed between TPPs and consumers, and that the TPPs acted within the scope of their authority in supposedly “agreeing” on behalf of consumers to pay inflated prices for Defendants' products. *See, e.g., Exchange Realty Co. v. Bines*, 302 Mass. 93, 97, 18 N.E.2d 425, 428 (1939) (holding that a legal secretary's lack of authority prevented her knowledge from being imputed to attorney); *Mann v. United Motor Boston Co.*, 226 Mass. 495, 497-98, 116 N.E. 239 (1917) (holding that notice that came to the agent before the agency relationship began is not charged to the principal). Defendants have made no showing that any consumers ever authorized TPPs to agree to pay inflated drug prices. It was for this reason that, after a lengthy evidentiary hearing and extensive briefing, the Honorable Joseph C. Visalli of the New Jersey Superior Court granted the plaintiff's motions *in limine* to bar evidence of purported insurer and government knowledge from the trial of plaintiff's claims of AWP inflation for Lupron in *Walker v. TAP Pharmaceutical Prods., Inc.*, Case No. CPM L-602-1.

This will keep the focus on the Medicare Part B program and produce at least some consistent findings with potentially preclusive future effect on the Class 3 claims. For instance, Plaintiffs expect that findings that one or more Defendants engaged in unfair or deceptive acts or practices would be accorded collateral estoppel effect in the Class 3 trial. Thus, even if the Class 3 claims are not included per se in the Class 1 and 2 trials, many of the factual issues tried *vis-à-vis* Classes 1 and 2 will be determinative for Class 3.

Concomitantly, the *Daubert* challenges considered in September would be limited to those issues relevant to Classes 1 and 2, thereby permitting the Court and parties to defer addressing *Daubert* challenges to Dr. Hartman's "expectations" theory, which is not relevant to the claims of either Classes 1 and 2.

**III. THE MOST EFFICIENT MANNER OF TRYING THIS CASE IS
TO TRY THE CLASS 1 AND 2 CLAIMS TOGETHER,
FOLLOWED BY THE CLASS 3 CLAIMS**

A. If Notice Concerns Militate In Favor Of Deferring The Trial Of The Class 1 Claims Until The Spring, Then The Class 2 Trial Should Be Deferred As Well

The Court has expressed concern with beginning the Class 1 trial before class notice has been provided. If the Court is not inclined to try the Class 1 and 2 claims in November given these concerns, the Court should defer the beginning of trial to March.

There are many common issues to be decided across Classes 1 and 2 that are most amenable to resolution in a single trial. They include:

- Use of AWP as the Medicare Part B reimbursement benchmark;
- The Classes' reimbursements based on AWP;
- Defendants' control over the published AWPs;
- Proof that the published AWP used for reimbursement was not an average price;

- Plaintiffs' proof of class-wide injury/aggregate damages.

The Class 1 and 2 Plaintiffs will introduce evidence on each of these issues in order to prove their claims, and Defendants will have common defenses. In other words, the evidence and expert testimony on these issues will be the same or similar across both Classes. Consequently, addressing all of these issues in a single trial is the most efficient manner in which to try the claims against the Track 1 Defendants and will ensure that issues are not tried duplicatively and resources are not squandered. There is simply no synergy to trying the TPP claims of Class 2 without also considering issues relevant to the consumer members of Class 1. In the alternative to a partial trial in November, Plaintiffs propose to begin trial on all issues and for Classes 1 and 2 in March after notice to all class members has been provided and after the Court has issued its summary judgment ruling and rulings on Class 1 and 2 *Daubert* issues.

Beginning the trial in Spring 2007 in this manner instead of November will still permit the Court to resolve meaningful, substantive issues this Fall, as the Court wishes to do. Relieved of the burden associated with beginning trial on issues that are not cleanly segregated from the common issues that bind all class members, the Court and parties can focus more intently on the Class 1 and 2 *Daubert* issues. The Court will also be called upon to confront and decide a number of other pressing AWP issues in the Fall. These issues include resolution of the Track 1 motions for summary judgment regarding Class 3. Furthermore, there are numerous motions to compel pending in Track 2, and the Court will have to evaluate and establish a schedule governing the close of Track 2 discovery and follow-on motions for summary judgment there. Thus, even without starting trial in the Fall, the AWP litigation will consume a substantial amount of the Court's time and energies (and that of the parties).

Finally, resolving the *Daubert* issues and summary judgment motions in the Fall will better frame the issues left to be tried in the Spring and provide the parties with ample time to prepare for trial based on the Court's rulings.

IV. THE COURT SHOULD CONSOLIDATE THE TRIALS OF ALL TRACK 1 DEFENDANTS INTO A SINGLE, JOINT TRIAL

During the July 6 hearing, the Court properly recognized that, instead of having trial proceed against each Track 1 Defendant individually, that trial should proceed against Track 1 Defendants jointly. *See* July 6 Hearing Tr. at 51. In so stating, the Court recognized that common, industry-wide issues recommend proceeding in this manner. *Id.*

Fed. R. Civ. P. 42(a) authorizes the Court to hold a joint trial “[w]hen actions involving a common question of law or fact are pending” Rather than try each case against each of the Track 1 Defendants *ad seriatim*, which would entail much duplication in the presentation of fact and expert evidence, the trial should proceed against all Track 1 Defendants jointly. This will avoid the repeated introduction of testimony and other evidence relating to, *inter alia*, topics such as the Medicare Part B program, the structure and participants in the Medi-Gap insurance market, expert testimony on matters of general applicability such as expectations theory for Class 3 and general liability and damages models for all Classes.

V. THE COURT SHOULD EMPLOY VARIOUS TECHNIQUES TO ENHANCE TRIAL EFFICIENCY

Rule 16(c) provides the Court with broad discretion to formulate strategies to “facilitate the just, speedy, and inexpensive disposition of the action,” Fed. R. Civ. P. 16(c)(16), including but not limited to employing orders to avoid unnecessary proof and cumulative evidence and establishing reasonable limits on the time allowed for presenting evidence. Fed. R. Civ. P. 16(c)(4) and (15). The Court is also encouraged to adopt “special procedures for managing

potentially difficult or protracted actions that may involve complex issues, multiple parties, difficult legal questions, or unusual proof problems.” Fed. R. Civ. P. 16(c)(12). Plaintiffs propose that the Court employ the following devices to enhance trial efficiency.

1. Time Limits

The MANUAL FOR COMPLEX LITIGATION FOURTH ANNOTATED (the “MANUAL”) encourages the use of time limits such as controlling the length of examination and cross-examination of particular witnesses and/or by limiting the total time allowed to each side for all direct and cross-examination. MANUAL, §§ 11.644, at 146-47. Given Defendants’ scorched-earth approach to this litigation, Plaintiffs predict that Defendants will seek to employ the same approach at trial, ensuring that it will be of excessive length if not tightly controlled by the Court. To that end, Plaintiffs propose that each side be limited to 50 hours for direct and cross-examination. The parties would then be free to allocate time as they wish across all witnesses and between direct and cross-examination. This will also encourage the parties to rely on common evidence, including testimony provided by common experts.

2. Limiting Experts

Defendants have already designated numerous experts to testify on overlapping common issues. The Court should limit the number of common-issue expert witnesses⁴ actually called at trial. *See, e.g., In re Factor VIII or IX Concentrate Blood Prods. Litig.*, 169 F.R.D. 632, 641-42 (N.D. Ill. 1996) (in blood-factor litigation involving over 192 cases, the court pared defendants’ identification of 137 common-issue experts to 35 for purposes of pre-trial discovery, reasoning that an expert providing testimony favorable to one defendant on an issue common to all

⁴ A “common-issue” expert is an expert who will be called to give opinion testimony on an issue that is common to all cases or all defendants. *Id.* at 638.

defendants will be benefiting all defendants). Defendants should be limited to one expert witness on any given issue.

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CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE

Docket No. MDL 1456

I, Steve W. Berman, hereby certify that I am one of plaintiffs' attorneys and that, on August 1, 2006, I caused copies of **PLAINTIFFS' STATUS REPORT FOR THE AUGUST 3 CONFERENCE AND PROPOSAL REGARDING THE TRACK 1 TRIAL** to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

/s/ Steve W. Berman

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